

## REMARKS

Claims 1, 3-4, 8, 12-16, 19, 21, 23-24, 26, 139-140, 143-144, 146-155, 159-160, and 162-193 are pending in the present application.

Claims 29, 141-142, 145, 156-158, and 161 are currently cancelled without prejudice or disclaimer to the subject matter recited there.

The amendments made to claims 1 and 21 in the Response filed on October 28, 2011 to recite the ratio range of water to alcohol as “1:1 to 1:3” are re-asserted herein, since the Examiner, in the Advisory Action dated November 3, 2011, declined to enter these amendments. In addition, claims 1 and 21 have been further amended to remove the “optionally” present components (namely, the “one or more penetration agents” and the “one or more excipients”), to specify that the pharmaceutical composition “contains one or more excipients suitable for forming a foam, aerosol, or mousse upon actuation”, and to positively recite “a propellant” as a component of the claimed composition. Support for these amendments appears throughout the specification and claims as originally filed.

Applicants have further added new claims 164-165, specifying that the “pharmaceutical composition forms a foam or mousse.”

In addition, applicants have added new claims 166-193. New claims 166 and 180 are

independent claims reciting a composition "consisting of: at least 5% by weight, based on the total weight of the composition, of minoxidil or a pharmaceutically acceptable minoxidil salt selected from the group consisting of minoxidil acetate, minoxidil citrate, minoxidil succinate, minoxidil benzoate, minoxidil hydrochloride, minoxidil sulphate, minoxidil phosphate, and minoxidil lactate, as sole hair-growing active present in the composition; an acid in an amount to substantially completely solubilize the minoxidil or the pharmaceutically acceptable minoxidil salt; a solvent of water and a lower alcohol wherein the ratio of water to alcohol is in a range of approximately 1:1 to 1:3 by volume; and a propellant; wherein the apparent pH of the final product is in the range of from 5.0 to 7.0".

Support for these new independent claims can be found in the original claims as filed and in the Abstract. New dependent claims 167-179 and 181-193 mirror the other dependent claims already pending in the present application.

No new matter has been added. Applicants, by amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any claim. Applicants reserve the right to reassert any of the claims canceled or the original claim scope of any claim amended herein, in a continuing application.

In view of the following, further and favorable consideration is respectfully requested.

In addition, Applicants respectfully incorporate herein by reference in their entirety the comments submitted in the Response filed on October 28, 2011 responsive to the pending rejections made by the Examiner. Accordingly, Applicants respectfully submit that the primary reference, JP 10-265343, for each of the outstanding obviousness rejections based on this reference does not constitute prior art against the instant application. In particular, claims 1 and 21 have been amended to claim the water to alcohol ratio of 1:1 to 1:3, which is recited in Australian Patent Application No. PP 3107. Thus, the instant claims are entitled to rely on the Australian priority date in that regard. Further, with respect to the Examiner's allegation that the Australian priority application does not disclose generic excipients, such as higher alcohols, vitamins preservatives, refrigerants, UV absorber, dye or gelling agent, Applicants submit that these "optional" embodiments have been removed from the presently pending claims.

Accordingly, the primary reference relied on by the Examiner in each of these obviousness rejections, JP 10-265343, does not qualify as prior art against the present application. Without the teachings of this primary reference, none of the other cited

reference teachings, whether taken alone or in combination, are sufficient to establish a case of *prima facie* obviousness against the present claims. Accordingly, withdrawal of each of these rejections under 35 U.S.C. §103(a) is requested.

Regarding the obviousness rejections based on Navarro et al., Applicants submit that the transition language "consisting of" recited with respect to the pharmaceutical compositions in each of the currently pending independent claims excludes components other than those expressly recited. Accordingly, the presently pending claims 1 and 21 clearly exclude encapsulation in lipid vesicles and/or in a cyclodextrin carrier, which is clearly an essential element of Navarro et al. for the reasons stated in the previous Response. In view of the foregoing, it is submitted that nothing in Navarro et al., along with the various combinations of secondary references, taken alone or together, renders the presently pending claims obvious within the meaning of 35 USC § 103. Accordingly, withdrawal of each of these rejections under 35 U.S.C. §103(a) is requested.

### **CONCLUSION**

Applicants assert that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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